46. The method of claim 45, wherein the hyperglycemia is due to a condition selected from organic disorder of pancreatic tissues, chronic hepatopathy, endocrinopathy, brain hypertension, adiposis, hyperphagia, crapula of alcohol, postgastrectomy, nutritional

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hyperglycemia, fibrile disease, carbon monoxide poisoning, increase of blood sugar due to drugs, and combinations thereof.---

REMARKS

Reconsideration and withdrawal of the rejections made in the mentioned Office Action are respectfully requested, in view of the foregoing amendments and the following remarks.

Summary of Amendments

By the foregoing amendments claims 2-21 are canceled and new claims 22-46 are added, whereby claims 1 and 22-46 are pending in the present application. Claims 1, 22, 33, 41 and 42 are independent claims. Support for the added claims can be found throughout the specification and, particularly, in claims 1 to 7 and at page 9 of the instant application.

It is noted that the cancellation of claims 2-21 is without prejudice or disclaimer to the prosecution of these claims in one or more divisional and/or continuation applications.

Summary of Office Action

As an initial matter, Applicants note with appreciation that the claim for foreign priority under 35 U.S.C. § 119(a)-(d) and receipt of the certified copies of the priority documents in this national stage application from the International Bureau have been acknowledged in the present Office Action and that an initialed and signed copy of Form PTO-1449 filed on August 21, 2002 has been returned together with the Office Action.

Claims 1-21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Claims 1-21 are rejected also under 35 U.S.C. § 102(b) as being anticipated by Youichirou et al., JP 10/130153 A (referred to in the Office Action as "Japan Patent (3)"[1]).

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested.

Response to Rejection under 35 U.S.C. § 112, First Paragraph

Claims 1-21 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to enable one

[1]Applicants assume that "Japan Patent (3)" denotes the third Japanese patent document listed in the Information Disclosure Statement filed August 21, 2002. Should this understanding not be correct, the Examiner is respectfully requested to clearly identify the cited document in another non-final Office Action to give Applicants the opportunity to address the correct document.

skilled in the art to make and/or use the invention. In particular, the Examiner takes the position that the instant application does not contain any test results or experimental data showing the instant medicament will, in fact, prevent diabetes or diabetes complications especially in a mammal not presently at risk of or predisposed to developing such a disease.

Applicants respectfully submit that this rejection is improper for at least the following reasons. In particular, it is noted that the Office Action does not provide any explanation as to why the Examiner is of the opinion that the mixture of polylactic acids recited in the present claims will not work for the prevention of diabetes or diabetes complications, much less has the Examiner cited any literature supporting this position. In this regard, the Examiner is reminded that it is the burden of the U.S. Patent and Trademark Office to prove a lack of enablement. For example, In re Marzocchi, 439 F.2d 220, 224, 169 U.S.P.Q. 367, 369 (CCPA 1971), states:

> [I]t is incumbent upon the Patent Office, whenever a rejection on this basis [lack of enablement] is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Id. at 370 (emphasis in original). Therefore, the burden of showing lack of enablement is on the Patent and Trademark Office. In the absence of any indication as to why the Examiner believes that the mixture of polylactic acids recited in the present claims is not effective in the prevention of diabetes or diabetes complications, Applicants are not in a position to address the Examiner's concerns. In the event that such basis is provided in the next Office

Action, Applicants respectfully request that the Action be made non-final, so that Applicants will have a full and fair opportunity to respond thereto.

In addition to the above, it is respectfully submitted that contrary to what is stated in the present Office Action, Applicants' specification does indeed contain test results showing that the administration of the recited mixture of polylactic acids (CPL) is effective in preventing diabetes. In this regard, the results given in Test Example 1 and illustrated in Figures 2 and 3 of the present application show that the blood sugar level can be reduced by administering CPL. It is common knowledge that diabetes can be prevented by increasing the blood sugar level. Accordingly, the results of Test Example 1 show that CPL is effective in preventing diabetes. It goes without saying that if diabetes can be prevented, complications arising from diabetes can be prevented as well. The same apparently applies if diabetes can be treated, i.e., if diabetes can be treated, complications arising from diabetes can not only be treated, but also prevented. (In this regard, it is noted that independent claim 41 does not recite the prevention of diabetes as such, but the prevention of complications arising from diabetes, wherefore this claim is clearly enabled for this reason alone.)

Furthermore, enclosed herewith is a Declaration under 37 C.F.R. § 1.132 by one of the inventors which describes additional experiments carried out under the supervision of the inventor. As set forth in the Declaration, the results of these experiments show that by administering the recited mixture of polylactic acids to a model mouse with moderately high blood sugar level, the morphology of islet of Langerhans can be maintained, the blood sugar

level can be maintained within the normal range, and the transition from moderately high blood sugar level to type II diabetes can be prevented and thus, the onset of diabetes can be prevented.

In view of the foregoing, Applicants submit that the rejection under 35 U.S.C. § 112, first paragraph is improper and should be withdrawn, which action is respectfully requested.

Response to Rejection under 35 U.S.C. § 102(b)

Claims 1-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Youichirou et al., JP 10/130153 A. In this regard, the rejection alleges that the cited document teaches a medicament (an anti-malignant tumor agent) comprising a cyclic and straight-chain mixed poly L-lactic acid having 3-19 degree condensation. The Examiner also compares the preparation process disclosed in the Japanese document with that of the present specification and takes the position that the cited document teaches and anticipates all of the Applicant's medicament and procedure for the production of this medicament.

Applicants note that the medicament of claim 1 is for the prevention/treatment of diabetes/diabetes complications. In comparison thereto, the agent of the cited document is an anti-malignant tumor agent. Although the intended use of the claimed medicament is recited in the preamble of claim 1, the preamble in this case gives life, meaning and vitality to claim 1. In particular, one of ordinary skill in the art would not assume that a medicament for the treatment of a malignant tumor contains the same excipient(s), auxiliary agent(s) etc.

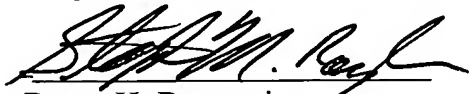
as a medicament for the treatment/prevention of diabetes (complications). Accordingly, the rejection of claim 1 under 35 U.S.C. § 102(b) is improper and withdrawal thereof is respectfully requested.

Applicants further note that the remaining pending claims, i.e., claims 22-46 submitted herewith, are directed to methods of treating/preventing diabetes and complications arising from diabetes, and of reducing the blood sugar level in a subject, i.e., not to a medicament or a procedure for the production of a medicament. Since the cited document does not appear to disclose any of the methods recited in claims 22-46, the rejection under 35 U.S.C. § 102(b) with repect to claims 22-46 is rendered moot.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to telephone the undersigned at the telephone number below.

Respectfully submitted,
Shigeo TAKADA et al.



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Annex: Declaration under 37 C.F.R. § 1.132